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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,515	12/22/2003	Ulrich J. Pfeiffer	PFEIFFER ET AL.-1	8194

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EXAMINER	
MALLARI, PATRICIA C	
ART UNIT	PAPER NUMBER
3735	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/743,515	PFEIFFER ET AL.	
	Examiner	Art Unit	
	Patricia C. Mallari	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *11-29 and 40-58* is/are allowed.

6)☒ Claim(s) *1-10 and 30-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/06,2/06,12/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

The election requirement between species I and II is hereby withdrawn.

Claims 11 and 41, which are generic to species A, B, C, D, E, and F, have been found allowable. All claims which depend from or otherwise require all the limitations of these allowable generic claims have been rejoined. Therefore, the election requirement between subspecies A-F has also be withdrawn.

Specification

The disclosure is objected to because of the following informalities:

In the equation on p. 18 of the specification, "PIT" should be replaced with "P_{IT}".

Any instance of "wind kessel" should be replaced with "Windkessel".

Appropriate correction is required.

Claim Objections

Claims 5, 6, and 34 are objected to because of the following informalities:

On lines 2-3 of claim 5, "wind kessel" should be replaced with "Windkessel".

On line 2 of claim 34, "wind kessel" should be replaced with "Windkessel".

On line 13 of claim 6, "Ptransmural" should be replaced with "$P_{transmural}$".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 and 30-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites, "a corrective function based on said second reading". However, on pp. 18-19 of the instant specification, the applicants identify a "corrective function" f(C) being a function of compliance (C) of the arterial system or primarily the aorta and the compliance is determined according to a non-linear Windkessel model. The specification does not set forth a "corrective" function based on the second reading, or a reading which at least approximately indicates the patient's intrathoracic pressure or is dependent on the same. The specification does set forth a derivation for the determination of transmural pressure, but this derivation is not identified as a "corrective" function as f(C) is identified. Claim 6, which ultimately depends on claim 1, identifies the derivation of the transmural pressure as the "corrective function". It is therefore unclear whether f(C) is a corrective function, the derivation of the transmural pressure is a corrective function, or both are considered to be "corrective".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 9, 10, 30, 38, and 39 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Application Publication No. 2003/0120164 to Nielsen et al. Nielsen teaches an apparatus for the continuous determination of a parameter characterizing a patient's left ventricular pumping action. The apparatus comprises a first input channel 150 for continuous recording of a variable physiological first reading directly dependent on the left ventricular pumping action (blood pressure or arterial pressure; see entire document, especially paragraph 52 of Nielsen) and a second input channel 150 for continuous recording of a variable physiological second reading (pulmonary artery wedge pressure PAWP or central venous pressure CVP; see entire document, especially paragraph 52 of Nielsen) which at least approximately indicates the patient's intrathoracic pressure (ITP) or is dependent on the same (see entire document, especially fig. 1; paragraphs 28, 31, 43, 45, 47, and 52; table 2 of Nielsen). An evaluation unit 175 calculates the parameter characterizing the patient's left ventricular pumping action from the first reading (left ventricular stroke work index or LVSWI), using a corrective function based on the second reading, wherein the derivation/formula LVSWI = (MAP-PAWP) * SI *0.0136 (SI is stroke index, MAP is mean arterial pressure from the blood pressure or arterial pressure input) is a corrective function based on the second reading PAWP. Alternatively, the evaluation unit calculates the systemic vascular resistance SVR, wherein SVR is a parameter characterizing the left ventricular pumping action, in that the parameter characterizes the pumping action required of the left ventricle. The derivation/formula SVR = 80 *

((MAP-CVP)/CO, wherein CO is cardiac output, the formula being a corrective function based on the second reading CVP (see entire document, especially fig. 8; paragraph 43, 56; table 2 of Nielsen).

Regarding claims 2 and 5, the first input channel is configured for reading a pressure transducer signal, wherein the first reading at least approximately corresponds to the patient's aortic pressure (see entire document, especially paragraph 52 of Nielsen), and wherein programming of the evaluation unit would allow one to calculate the parameter characterizing the patient's left ventricular pumping action by means of a pulse contour analysis. The applicants should note that the language in claim 2 does not specify that the programming of the evaluation unit requires the evaluation unit itself to calculate the parameter characterizing the patient' left ventricular pumping action by means of a pulse contour analysis, only that such calculation be possible. Similarly and with regard to claim 5, the pulse contour analysis may be based on a non-linear Windkessel model, wherein, again, the claim language does not require the evaluation unit to conduct the pulse contour analysis based on the non-linear Windkessel model.

Regarding claim 3, the first reading which at least approximately corresponds to the aortic pressure is an arterial pressure (see entire document, especially paragraph 52 of Nielsen).

Regarding claim 4, the arterial pressure is a pressure measured close to the aorta (see entire document, especially paragraphs 47 and 52 of Nielsen), wherein the measurement of the arterial pressure at any point on the patient's body is considered "close to the aorta".

Regarding claims 9 and 38, the second input channel is configured for reading a pressure transducer signal (see entire document, especially paragraph 52 of Nielsen), wherein the second reading at least approximately corresponds to the patient's central venous pressure, the PAWP at least approximately corresponding to the CVP, or the second reading being CVP.

Regarding claims 10 and 39, the parameter characterizing the patient's left ventricular pumping action (SVR or LVSWI) is a parameter directly calculated from cardiac output or stroke volume, wherein stroke index is directly dependent upon stroke volume (see entire document, especially table 2 of Nielsen).

Regarding claims 30, 38, and 39, the description of the apparatus of Nielsen inherently delineates a method of operating the apparatus, such that the apparatus of Nielsen clearly records the first and second variable physiological readings and calculates the parameter characterizing the left ventricular pumping action as described above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen, as applied to claims 1-5, 9, 10, 30, 38, and 39 above, and further in view of US

Patent No. 5,316,004 to Chesney et al. Nielsen lacks calculating the parameter characterizing the left ventricular pumping action by means of a pulse contour analysis, but teaches calculating stroke volume (SV) and cardiac output (CO) and calculating the left ventricular pumping action parameter (SVR or LVSWI) using the stroke volume and/or cardiac output. However, Chesney teaches determining cardiac output and stroke volume based on pulse contour analysis (see entire document, especially col. 3, lines 1-25; col. 3, line 46-col. 4, line 9; col. 4, line 25-col. 5, line 34 of Chesney), wherein determination of the cardiac output and stroke volume is based on analysis of the pulse waveform or pulse contour. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the method of Chesney to determine cardiac output and/or stroke volume, in places of that of Nielsen, as it would merely be the substitution of one means of cardiac output and/or stroke volume determination for another.

Regarding claim 32, the first reading at least approximately corresponds to the aortic pressure and is an arterial pressure ((see entire document, especially paragraph 52 of Nielsen).

Regarding claim 33, the arterial pressure is a pressure measured close to the aorta (see entire document, especially paragraphs 47 and 52 of Nielsen), wherein the measurement of the arterial pressure at any point on the patient's body is considered "close to the aorta".

Allowable Subject Matter

Claims 6-8, and 34-37 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claims 11-29 and 40-58 are allowed.

The following is a statement of reasons for the indication of allowable subject matter:

With regard to claims 6-8 and 35-37, the prior art of record fails to teach or fairly suggest the apparatus or method for continuous determination of a parameter characterizing a patient's left ventricular pumping action, wherein the corrective function has the form of

$$P_{transmural} = Pao - f(C) \times P_{IT}$$

wherein Pao is the first reading which at least approximately corresponds to the aortic pressure, P_{IT} is the second reading which at least approximately expresses the intrathoracic pressure (ITP), and f(C) is a function which depends on the compliance (C) of the arterial system or the aorta and which increases monotonically as the compliance increases and may assume values between 0 and 1, and wherein the transmural pressure ($P_{transmural}$) is the determining pressure in the pulse contour analysis, in combination with all of the other limitations of the claims.

With regard to claim 34, the prior art of record fails to teach or fairly suggest the method of continuous determination of a parameter characterizing a patient's left ventricular pumping action wherein the parameter characterizing the patient's left ventricular pumping action is calculated by means of a pulse contour analysis, wherein

the pulse contour analysis is based on a non-linear Windkessel model, in combination with all of the other limitations of the claims. US Patent No. 5,316,004 to Chesney et al. teaches pulse contour analysis based on a non-linear Windkessel model, which is used to determine peripheral resistance R, wherein R is a parameter characterizing the left ventricular pumping action required and the calculation of R is based on a first reading (arterial pressure or mean arterial pressure MAP) directly dependent on the left ventricular pumping action (see entire document, especially fig. 1; col. 6, line 27-col. 7, line 33 of Chesney). However, the calculation of R does not also use a corrective function based on a second reading which at least approximately indicates the patient's intrathoracic pressure (ITP) or is dependent on the same. Furthermore, there is no motivation to combine the pulse contour analysis based on the nonlinear Windkessel model with the method of US Patent Application Publication No. 2003/0120164.

With regard to claims 11-29 and 40-58, the prior art of record fails to teach or fairly suggest a method or apparatus for the continuous determination of a cardiac volume responsiveness indicator, wherein the second reading, at least approximately representing the patient's intrathoracic pressure, and the third reading, which directly depends on the patient's state of respiration, are used to select a function that can be used for the patient's current state of respiration and the volume responsiveness indicator is calculated based on this function and from the first reading, which is directly dependent on a patient's left ventricular pumping action, and the second reading, in combination with all of the other limitations of the claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

US Patent No. 6,017,313 to Bratteli et al. discloses a pulse contour analysis based on a nonlinear Windkessel model.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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